

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ALLOS THERAPEUTICS, INC., SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH; SOUTHERN RESEARCH INSTITUTE; and SRI INTERNATIONAL, INC.,

Plaintiffs,

V.

C. A. No. 14-778-RGA

TEVA PHARMACEUTICALS USA, INC.; SANDOZ INC.; FRESENIUS KABI USA, LLC; DR. REDDY'S LABORATORIES, LTD.; DR. REDDY'S LABORATORIES, INC.,

Defendants.

STIPULATION AND ORDER

Plaintiffs Allos Therapeutics, Inc. (“Allos”), Sloan-Kettering Institute For Cancer Research (“Sloan-Kettering”), Southern Research Institute (“Southern Research”), and SRI International, Inc. (“SRI”) (collectively, “Plaintiffs”) and Defendants Dr. Reddy’s Laboratories, Ltd. and Dr. Reddy’s Laboratories, Inc. (collectively, “Dr. Reddy’s”) by their undersigned counsel, stipulate and agree as follows:

WHEREAS Dr. Reddy's submitted Abbreviated New Drug Application No. 206183 ("Dr. Reddy's ANDA") to obtain approval from the FDA to engage in the commercial manufacture, use, and/or sale of generic pralatrexate injection solution 20 mg (1 ml) and 40 mg (2ml) products ("Dr. Reddy's ANDA Products");

WHEREAS Sloan-Kettering, SRI, and Southern Research represent that they own U.S.

Patent No. 6,028,071 (the “’071 Patent”);

WHEREAS Sloan-Kettering represents that it owns U.S. Patent No. 7,622,470 (the “’470 Patent”) and U.S. Patent No. 8,299,078 (the “’078 Patent”);

WHEREAS Allos represents that it is an exclusive licensee of the ’071 Patent, ’470 Patent, and ’078 Patent, and holds approved New Drug Application No. 022468 for Folutyn® pralatrexate intravenous injection solution 20 mg (1 ml) and 40 mg (2ml) products;

WHEREAS Plaintiffs sued Dr. Reddy’s for infringement of the ’071, ’470, and ’078 Patents in this Court on June 19, 2014 (“the Dr. Reddy’s Action”);

WHEREAS Plaintiffs have provided Dr. Reddy’s with a Covenant Not to Sue with respect to the ’071 Patent;

WHEREAS Plaintiffs assert that Dr. Reddy’s infringed claims 1-6, 9-12, 15-20, 23-28, 31-36, 39-43, 46-52, and 55-68 of the ’470 Patent, and claims 1-6 and 9-27 of the ’078 Patent (collectively, the “Asserted Claims”) by filing Dr. Reddy’s ANDA, and that the manufacture, use, offer for sale, sale, and/or importation of Dr. Reddy’s ANDA Products will infringe the Asserted Claims;

NOW, THEREFORE, Plaintiffs and Dr. Reddy’s, their successors and assigns hereby stipulate for purposes of this litigation only, and will not contest before this Court or on appeal, as follows:

1. Plaintiffs and Dr. Reddy’s agree that all claims, counterclaims, and defenses as between Plaintiffs and Dr. Reddy’s with respect to the ’071 patent are dismissed without prejudice.

2. This stipulation shall have no effect on the claims, counterclaims, and defenses with respect to U.S. Patent No. 7,622,470 and U.S. Patent No. 8,299,078, which remain in suit as between Plaintiffs and Dr. Reddy's.

3. The submission of Dr. Reddy's ANDA to the FDA infringes the Asserted Claims under 35 U.S.C. § 271(e)(2)(A), provided those claims continue to be asserted against Dr. Reddy's and are not found to be invalid or unenforceable.

4. Upon final approval of Dr. Reddy's ANDA, Dr. Reddy's ANDA Products or the administration of Dr. Reddy's ANDA Products according to their indicated use will infringe the Asserted Claims, provided those claims continue to be asserted against Dr. Reddy's and are not found to be invalid or unenforceable.

5. Except for the Asserted Claims, Plaintiffs agree that they shall not assert any of the remaining claims of the '470 or '078 patents against Dr. Reddy's, its manufacturers, customers, distributors, successors, assigns, or anyone in privity therewith, in connection with Dr. Reddy's ANDA Products.

6. Nothing in this Order shall bar Plaintiffs or Dr. Reddy's from filing a notice of appeal from, or participating in any appeal of, any judgment that may be entered for or against Dr. Reddy's in the Dr. Reddy's Action with respect to issues of validity and/or unenforceability.

7. Following the entry of this Stipulation and Order, the Dr. Reddy's Action shall remain stayed in all respects, pending a joint motion by Plaintiffs and Dr. Reddy's to lift the stay for the purpose of entering a judgment or order with respect to claims, counterclaims, and/or defenses remaining in the Dr. Reddy's Action.

The foregoing is agreed to by:

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SO ORDERED this 31 day of May, 2016.


United States District Judge